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REMARKS

The Examiner is thanked for the very thorough and professional office action and for withdrawal of the objections to the drawings, specification and claims. In addition, the Examiner is thanked for withdrawal of the previous rejections under 35 U.S.C. 112, second paragraph, and all previous rejections under 35 U.S.C. 102 and 103. Pursuant to the office action, claims 6 and 14 have been amended in accordance with the Examiner's suggestions. Further, new claim 20 has been added which corresponds to claims 18 and 19 but is dependent upon claim 11. The present amendment is deemed not to introduce new matter, raise new issues, or require any additional search. Claims 1-20 are in the application, claims 1-5, 9, 10 and 16 having been withdrawn as being directed to a non-elected invention.

Reconsideration is respectfully requested of the objection to claims 6 and 14 as being unclear. These claims have been rewritten in the manner suggested by the Examiner to clarify any ambiguities. It is believed that the objection is now moot, and withdrawal of the objection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of claims 6-8, 14, 15, 18 and 19 under 35 U.S.C. 103(a) as being unpatentable over Kitajima, et al. in view of Kadoya.

THE INVENTION

The present invention provides a plasma or serum separating membrane enabling reliable and rapid separation of plasma or serum components from blood without causing breakage of erythrocytes. As a result of diligent research for separation of plasma or serum components from corpuscles in blood, the inventors of the present application found that plasma

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or serum components can be separated from corpuscles without causing hemolysis by using a separation membrane having pores of specific constitution and accomplished the present invention.

A plasma or serum separating membrane of the present invention is intended to separate plasma or serum from blood, and is characterized by having a porosity of not more than 30%. (Specification, page 3, lines 7-25)

A filter apparatus of the present invention comprises a first filter member through which plasma can move faster than corpuscles, and a plasma or serum separating membrane according to the present invention, serially connected in subsequent stage with the first filter member.

THE KITAJIMA, ET AL. PATENT

Kitajima, et al. discloses in Fig. 1 a conventional device used to prepare plasma or serum samples from whole blood. This apparatus incorporates multiple filter elements and materials described in Kitajima, et al. at column 5, line 45, through column 8.

In the rejection, the Examiner relies upon Kitajima, et al. as a primary or principal reference. The Examiner states in the rejection that Kitajima, et al. fails to teach that the first filter member has a packing density of a downstream part higher than a packing density of an upstream part in the filter member.

In the rejection the Examiner also states that Kitajima, et al. teaches a filter unit comprising a first filter member 10 and a microporous membrane 13 having a porosity of not more than 30%. In support of this teaching the Examiner relies upon Kitajima, et al. in column 1, lines 58-64, column 2, lines 45-62, column 5, lines 46-52, column 6, lines 1-27, column 9, lines 14-20, and Example 1.

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However, after a careful review it is earnestly and respectfully submitted that Kitajima, et al. does not disclose nor suggest using a microporous membrane having such a porosity. In particular, column 6, lines 1-27, of Kitajima, et al. discloses that the porosity of the microporous membrane is preferably 40 – 95%, more preferably 50 – 95%, and further preferably 70 – 95% . Accordingly, the prior art teaches that high porosity is rather suitable and does not disclose nor suggest a low porosity of not more than 30%.

In addition, in column 9, lines 14-20 of Kitajima, et al., a range of 10% or more, preferably 20 - 100% and more preferably 30 – 70% are described. This range is, however, not the porosity of the microporous membrane 13, but a volume of plasma or serum to be covered. Thus, the range shown in column 9, lines 14-20, has nothing to do with the porosity of the microporous membrane 13.

Moreover, the disclosure of '20% or less' in column 2, line 38 of Kitajima, et al., also means a mere amount of volume of blood, not the porosity of the microporous membrane 13. Further, in Example 1 of Kitajima, et al., the porosity of the microporous membrane 13 is not disclosed. Thus, an important feature of the present invention required by the claims herein is neither disclosed nor suggested by Kitajima, et al.

According to the present invention, in the first filter¹⁰, plasma or serum moves rapidly as compared to corpuscles and, thus, the plasma or serum first reaches the plasma or serum separating membrane having a porosity of not more than 30%; and then flows through this separating membrane. In contrast, the corpuscles move slowly to and through the first filter

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before reaching the plasma or separating membrane. But these corpuscles cannot, however, pass through the separating membrane.

In summary, the Examiner's primary or principal reference of Kitajima, et al. fails to teach or suggest two important features required by claim 6, i.e.:

A first filter member through which plasma can move faster than corpuscles, said first filter member having an upstream and downstream part and having a packing density of a downstream part higher than a packing density of an upstream part in the filter member, and

2. plasma or serum separating membrane for separating plasma or serum from blood, said separating membrane having a porosity of not more than 30%.

THE KADOYA PATENT

In an effort to cure the deficiencies of Kitajima, et al. discussed above, the Examiner relies upon the secondary reference of Kadoya which is concerned with a multi-layer filter medium of a non-woven fabric of a lower fiber density laminated to a filter paper of a higher fiber density. The multi-layer filter medium of Kadoya is designed for use as an oil filter or air filter for an internal combustion engine. There is no suggestion in Kadoya that the multi-layer filter medium could be used for the separation of plasma or serum components from blood without causing breakage of erythrocytes.

In particular, Kadoya discloses that relatively large particles are trapped by the upstream non-woven fabric to promote the formation of a dust cake layer on the surface of the filter paper. The surface trapping may prevent the particles from being embedded within the filter medium, thus preventing the filter medium from being clogged therein (column2, lines 14-24). Further, the filter of Kadoya was developed for preventing clogging of the filter by dust particles, and

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thus the feature of the present invention, i.e., increasing the difference between moving speeds of the plasma and serum and corpuscles in blood cannot be found in the secondary reference.

It is clear from the above that the Kadoya patent is non-analogous art with respect to the problem the present inventors sought to solve which is to provide a filter apparatus to separate serum or plasma components from corpuscles in blood without causing hemolysis.

There is no teaching or suggestion in either of the Examiner's primary or principal references that they can be combined in the manner suggested in the rejection. In this same connection, the problems being solved were different, and the material being filtered was different. Further, there is no disclosure in Kadoya of employing with the multi-layer filter medium a plasma or serum separating membrane for separating plasma or serum from blood, with the separating membrane having a porosity of not more than 30% and being serially connected in a subsequent stage with the first filter member. Further, there is no motivation to combine the oil filter for a combustion engine of Kadoya with the blood separation apparatus of Kitajima, et al. since the problem being solved is different and the solution to that problem is different.

In view of the foregoing, it is strongly urged that it would not be obvious to combine the references in the manner suggested by the Examiner because these references are concerned with entirely different arts, i.e., filtering blood in the case of Kitajima, et al., and filtering either oil or air for an internal combustion engine in the case of Kadoya. Moreover, even if these references were combined in the manner suggested by the Examiner, there is still no teaching or suggestion of employing in the filter medium a plasma or serum separating membrane for separating plasma and serum from blood with the separating membrane having a porosity of not more than 30%,

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and being serially connected in a subsequent stage to the first filter medium. On the contrary, that teaching or suggestion comes only from the present application, and constitutes an important element or aspect of the invention.

In the recently published "Examination Guidelines For Determining Obviousness Under 35 U.S.C. 103 In View Of The Supreme Court Decision in KSR International Co. v. Teleflex, Inc.", (Federal Register/Vol. 72, No. 195/October 10, 2007/Notices) the U.S. PTO stated:

"To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Office personnel must then articulate the following:

- (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference;
- (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it did separately;
- (3) a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable; and
- (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness."

As rationale for the above requirements the office relied upon the authority of KSR at 82 USPQ 2d at 1395 (2007); *Sakraida v. AG Pro, Inc.*, 425 US 273, 189 USPQ 449, 453 (1976); *Anderson's - Black Rock, Inc. v. Pavement Salvage Co.*, 396 US 57, 62-63, 163 USPQ 673, 675

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(1969); and *Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp.* 340 US 147, 152, 87 USPQ 303, 306 (1950).

In the present case, it is respectfully and sincerely urged that the rejection based on Kitajima, et al. in view of Kadoya utterly fails to comply with the requirement for a *Graham* factual inquiry as discussed above. Most important is the fact that these prior art references do not include each element claimed as pointed out above. Moreover, the rejection fails to make a finding that each element would have performed the same function as it did in the separate references. Consequently, it is respectfully submitted that the rejection fails, as a matter of law, in view of the above authorities. Therefore the Examiner would be justified in no longer maintaining this rejection. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of claim 11 under 35 U.S.C. 103(a) as being unpatentable over Kitajima, et al. in view of Kadoya as applied to claim 6, and further in view of Ayres.

The Kitajima, et al. and Kadoya references are discussed above.

It is respectfully requested that the Ayres reference does not cure the deficiencies of the primary and secondary references. Further, in claim 11 of the present application, the first filter member has the property of absorbing fibrinogen, and in claim 18 the first filter member is made of polyester-based resin. It is respectfully urged that the subject matter called for in claims 11 and 18 are nowhere disclosed in Kadoya. Kadoya merely discloses the filter member made of cellulose, and adsorbing property of such a filter member is considerably low as compared to the first filter member made of polyester-based resin.

It is therefore respectfully submitted that the rejection fails in view of these deficiencies

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in the applied prior art. Consequently, the Examiner would be justified in no longer maintaining the rejection. Withdrawal of the rejection is respectfully requested.

Reconsideration is requested of the rejection of claim 12 under 35 U.S.C. 103 (a) as being unpatentable over Kitajima, et al. in view of Kadoya, as applied to claim 6, and further in view of Bell.

The deficiencies of Kitajima, et al. and Kadoya patents are discussed above.

The Bell reference relied upon by the Examiner fails to cure the deficiencies of the primary and secondary references discussed above. Since claim 12 is dependent upon claim 6, it is respectfully submitted that the rejection fails, as a matter of law, for the same reasons discussed above with respect to claim 6. Consequently, the Examiner would be justified in no longer maintaining the rejection. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of claim 13 under 35 U.S.C. 103(a) as being unpatentable over Kitajima, et al. in view of Kadoya, as applied to claim 6, and further in view of Anraku.

The deficiencies of Kitajima, et al. and Kadoya patents are discussed above.

The Anraku reference relied upon by the Examiner fails to cure the deficiencies of the primary and secondary references discussed above. Since claim 13 is dependent upon claim 6, it is respectfully submitted that the rejection fails, as a matter of law, for the same reasons discussed above with respect to claim 6. Consequently, the Examiner would be justified in no longer maintaining the rejection. Withdrawal of the rejection is accordingly respectfully requested.

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Reconsideration is requested of the rejection of claim 17 under 35 U.S.C. 103(a) as being unpatentable over Kitajima, et al. in view of Kadoya, as applied to claim 6, and further in view of Chu.

The deficiencies of Kitajima, et al. and Kadoya patents are discussed above.

The Chu reference relied upon by the Examiner fails to cure the deficiencies of the primary and secondary references discussed above. Since claim 17 is dependent upon claim 6, it is respectfully submitted that the rejection fails, as a matter of law, for the same reasons discussed above with respect to claim 6. Consequently, the Examiner would be justified in no longer maintaining the rejection. Withdrawal of the rejection is accordingly respectfully requested.

Request For Withdrawal Of Final Rejection Under MPEP 706.07(a) And 706.07(d)

Applicant hereby respectfully requests reconsideration of the finality of the rejection mailed October 31, 2007 on the ground that it is premature. MPEP 706.07 provides, in pertinent part, that:

“---present practice does not sanction hasty and ill-considered rejections. The applicant who is seeking to define his or her invention in claims that will give him or her the patent protection to which he or she is justly entitled should receive the cooperation of the Examiner to that end, and not be prematurely cut off in the prosecution of his or her application.”

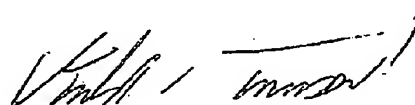
In the present case, all prior art rejections were withdrawn in the final rejection but new prior art rejections were applied based on the addition of the Kadoya reference to the other

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combination of references. Since Kadoya is taken from non-analogous art, does not solve the same problem as the present invention, and does not disclose the elements called for in the claims, these new rejections based on Kadoya may very well be considered hasty and ill-considered. It is therefore respectfully urged that the rejections based on a new combination of references is premature. Applicant therefore respectfully requests reconsideration and the cooperation of the Examiner to withdraw the finality of the rejections

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance, and early action and allowance thereof is accordingly respectfully requested. In the event there is any reason why the application cannot be allowed at the present time, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems.

Respectfully submitted,



Donald E. Townsend
Reg. No. 22,069

Date: February 20, 2008

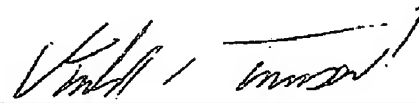
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CERTIFICATE OF TRANSMISSION

I hereby certify that this facsimile transmission, consisting of a 17-page Amendment After Final Rejection and Request For Withdrawal of Final Rejection under MPEP 706.07(c) and 706.07(d) in U.S. patent application serial No. 10/533,539, filed on May 2, 2005, is being facsimile transmitted to the U.S. Patent and Trademark Office (Fax no. 571-273-8300) on February 20, 2008.

A handwritten signature in black ink, appearing to read "Donald E. Townsend", is written over a horizontal line.

Donald E. Townsend